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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/493,427      | 01/29/2000  | Patrick L. Iverson   | 0450-0025.30        | 2225             |

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EXAMINER

EPPS FORD, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/493,427

Applicant(s)

IVERSON ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28,30,32-41,43 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41,43 and 45-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Arguments***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

2. Claims 41, 43, and 45-48 remain rejected under 35 USC 103(a) as being unpatentable over Zalewski et al. (US Patent No. 6,159,946) in view of Kobayashi et al., Summerton et al. (US Patent No. 5,378,841), Burger, and Agrawal et al. for the reasons of record set forth in the Office Action mailed 3-19-04.
3. Applicant's arguments filed 8-19-04 have been fully considered but they are not persuasive. Applicants stated that in the Office Action mailed 3-19-04, the Examiner reiterated the previous rejection on the grounds that the "patient" of the previous claims could encompass a non-human animal model, as shown in the Zalewski reference. According to Applicants, the Examiner acknowledged unexpected results demonstrated with administration of a phosphorodiamidate morpholino compound comprising SEQ ID NO: 1 for treatment of a human patient. Therefore, according to Applicants "[B]ecause the independent claims have been limited in accordance with this embodiment, the applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn. However, it is noticed that independent claim 41, drawn to an intravascular stent, and dependent claims 43, and 45-48 have not been amended to wherein the stent is used in a human patient. It remains that the scope of claims 41, 43, and 45-48 encompass the use of an intravascular stent in an animal as described in Zalewski et al. and Kobayashi et al. Therefore, as stated in the prior Office Action, absent evidence to the contrary, it would have

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been obvious to one of ordinary skill in the art at the time of filing of the instant application to modify the method of preventing restenosis in a patient as described by Zalewski et al. with the antisense oligonucleotide of Kobayashi et al. because this antisense oligonucleotide has been disclosed to function successfully in vitro and in vivo to reduce the expression of c-myc. Furthermore, one of skill in the art would have been motivated to use the antisense oligonucleotides of Kobayashi et al. (which comprises SEQ ID NO: 1 of the instant invention) because it would have been obvious to replace one functionally equivalent antisense oligonucleotide targeting c-myc with another. Additionally, absent evidence to the contrary it would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Zalewski et al. to comprise the administration of antisense oligonucleotides comprising internucleoside linkages having morpholino modifications as taught by Summerton et al. and Burger, and to comprise the use of a biodegradable stent as taught by Burger. One of ordinary skill in the art would have been motivated to use morpholino modified oligomers of Summerton et al. or Burger, because Burger clearly teach the reduction of restenosis in an animal comprising the administration of morpholino modified oligomers via a biodegradable stent. Furthermore, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art to modify the oligonucleotides of Zalewski et al. with triethyleneglycol modifications as described by Agrawal, since these modifications enhance the solubility of the antisense oligonucleotides.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45-48 recite "the stent of claim 44." There is lack of antecedent basis for this limitation in the instant claims since Applicants canceled claim 44.

***Conclusion***

6. Claims 28, 30, and 32-40 are free of the prior art of record.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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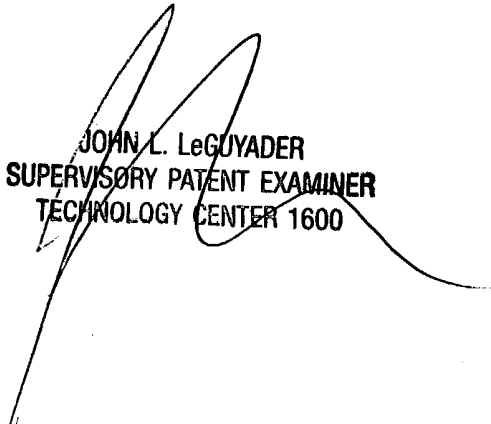
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford, Ph.D.  
Patent Examiner  
Art Unit 1635

*JLE*

  
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